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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Frommer Lawrence & Haug
745 Fifth Avenue
New York, NY 10151

EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT	PAPER NUMBER
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1655

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07/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/564,799	Applicant(s) TAGG ET AL.	
	Examiner Christopher R. Tate	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 11-15, 20-31, 33-39, 41 and 42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 11-15, 20-31, 33-39, 41 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>0806</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election (without agreeing to Examiner's assertions within the previous Office action) of the species *Eubacterium* in the reply filed on 01 May 2008 is acknowledged.

Upon further consideration by the Examiner, the election of species requirement set forth in the previous Office action is deemed unnecessary and is, therefore, withdrawn.

Accordingly, claims 1-7, 11-15, 20-31, 33-39, 41, and 42 have been examined on the merits, including with respect to all the bacterial species recited therein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 11-15, 20-31, 33-39, 41, and 42 not deemed enabled without complete evidence either that the claimed biological material (that is, the particular instantly claimed strains of BLIS-producing *Streptococcus salivarius* - i.e., strains K12 and K30) is known and readily available to the public or complete evidence of the deposit of the biological material.

It is apparent that the demonstrated biological material is required to practice the elected claimed invention. As a required element **it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification**. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a biological deposit thereof. See 37 C.F.R. § 1.802.

The specification does not provide a repeatable process for obtaining the demonstrated biological material and it is not apparent if the biological material is readily available to the public. The specification must contain the date that the biological deposited was made, the name of the biological material and the address of where the biological deposit was made.

If the deposit(s) has/have been made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney or record over his/her signature, and registration number, stating that the specific seed strain(s) has/have been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. § 1.808.

If the deposit(s) has/have not been made under the Budapest Treaty, then in order to certify that the deposits meet the criteria set forth in 37 C.F.R. § 1.801-1.809, Applicant(s) may provide assurance of compliance by an affidavit or declaration, or by a statement by an Attorney of record over his/her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

c) the deposit(s) will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a viability statement in accordance with the provisions of 37 C.F.R. § 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 C.F.R. § 1.809 (d) should be added to the specification. See 37 C.F.R. § 1.803-1.809 for additional explanation of these requirements.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 11-15, 20-31, 33-39, 41, and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In various claims, including independent claims 1, 3, 4, and 33, the phrase "BLIS-producing *S. salivarius*, [or] extract thereof". However, the phrase "extract thereof", in and of itself, does not adequately delineate its metes and bounds. This term is best defined as a product-by-process since product-by-process claims are intended to define products which are otherwise difficult to define (and/or distinguish from the prior art). For example, is the extract obtained via extraction with water, a polar solvent, a non-polar solvent, an acid or base, an extracted protein or portion/fragment thereof, an extracted nucleic acid or portion/fragment thereof, or something else? It is well accepted in the extraction art that extraction with one of various distinct solvents has a profound impact on the final product with respect to the presence, absence, amounts, and/or ratios of active ingredients therein and, thus, its ability to provide the desired functional effect(s)

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instantly claimed and/or disclosed. Accordingly, it is suggested that the instantly claimed extract be more fully defined (so as to clearly delineate its metes and bounds) via expanding the independent claims so as to recite the step(s) by which the extract is actually prepared (i.e., as a product-by-process) using the instant specification Examples as a guide (e.g., in Example 1, whereby the extract is prepared via methanolic extraction).

Claim 26 is rendered vague and indefinite by the phrase "wherein the secondary antibacterial agent(s) are selected from bacteriocin-like inhibitory substance(s)". This phrase is unclear because claim 26 ultimately depends from claim 3, which already defines the *Streptococcus salivarius* strain as one which is a BLIS (bacteriocin-like inhibitory substances) - producer. Based upon the definition provided by the instant specification, the BLIS produced by such a *S. salivarius* strain would already be comprised of bacteriocin-like inhibitory substances (such as salvaricin A and B) - e.g., as one or more primary antibacterial agents, therein. Accordingly, it is unclear if claim 26 is attempting to define that the BLIS-producing *S. salivarius* strain (or extract thereof) comprises additional amounts of such bacteriocin-like inhibitory substances (e.g., in addition to that which is already being produced by the BLIS-producing strain) or something else.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 11-15, and 20-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Tagg et al. (WO 01/27143).

A method for at least inhibiting the growth of anaerobic bacteria sensitive to BLIS-producing *S. salivarius* via contacting the sensitive bacteria with a BLIS-producing *S. salivarius*, or extract or composition thereof, is apparently claimed. Also claimed is a method of prophylactically treating halitosis in an individual in need thereof or reducing the incidence and/or or severity of halitosis in an individual susceptible to halitosis via administering thereto a BLIS-producing *S. salivarius*, or extract or composition thereof, in an amount effective to at least inhibit or colonize the oral cavity. Dependent claims include using a *S. salivarius* strain that produces one or more salivaricins including salivaricin A and salivaricin B- such as strain K12 or K30; orally administering the composition including in such forms as a lozenge, spray, mouth rinse, toothpaste, gargle, capsule, mouthwash, gargle, or toothpaste; using a second antibacterial agent; pretreating the individual so as to reduce the bacterial population in the oral cavity.

Tagg et al. teach a method of orally administering an effective amount of a BLIS-producing *S. salivarius* - in particular strains K12 and/or K30, or extract or composition thereof, to an individual so as to at least inhibit microorganisms in the upper respiratory tract such as the oral cavity of the individual (including prophylactic treatment thereof). Tagg et al. further teach

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using a secondary antibacterial agent (i.e., one or more salivaricins such as those instantly claimed); pretreating the individual so as to reduce the microbial population by orally administering an antibiotic such as erythromycin prior to the BLIS-producing *S. salivarius* treatment. Tagg et al. also teach the administering various oral composition forms thereof - including in the form of a lozenge, spray, mouth rinse, toothpaste, gargle, capsule, mouthwash, gargle, toothpaste, food, confectionery, or drink. In addition, Tagg et al. teaches administering the BLIS-producing *S. salivarius* so as to cause colonization thereof within at least a part of the upper respiratory tract including the mouth (see entire document including pages 2-5, 10-12, and 14-16). With respect to independent claim 1, please note that although the method disclosed by Tagg et al. is mainly drawn to treating (including prophylactically treating) pathogenic *Streptococcus* infections (which, please note, are considered anaerobic bacteria) in the upper respiratory tract and/or dental caries caused thereby, the administration of the BLIS-producing *S. salivarius* - in particular strains K12 and/or K30, or extract or composition thereof, to an individual - as expressly taught by Tagg et al., would inherently contact anaerobic bacteria sensitive to the BLIS-producing *S. salivarius* (since the normal flora of all individual, including all humans, is composed of a vast array of anaerobic bacteria - many of which would inherently be sensitive to the K12 and K30 strains). Further, with respect to independent claims 3 and 4, the method taught by Tagg et al. reads upon a method of prophylactically treating halitosis in an individual (instant claim 3) since such prophylactic treatment reads upon an individual who does not currently have halitosis and/or an individual who is not defined as having halitosis; as well as a method of controlling the incidence and/or severity of halitosis in an individual susceptible to halitosis (instant claim 4) since all individuals, including all humans, are susceptible to halitosis

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(i.e., no one is immune from having/experiencing bad breath), including those who do not currently have halitosis and/or who are not defined as having halitosis. Please also note that treating such an individual in a prophylactic manner (e.g., one who does not currently have halitosis) would inherently control the incidence and/or severity of halitosis caused by the various anaerobic bacteria instantly claimed.

Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 11-15, 20-31, 33-39, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tagg et al. (WO 01/27143), in view of Huatan et al (US 2001/0043941) and Chikindas et al. (US 5,672,351), and further in view of Kross (US 5,772,986).

Tagg et al. teach a method of orally administering an effective amount of a BLIS (Bacteriocin-Like Inhibitory Substances)-producing *S. salivarius* - in particular strains K12 and/or K30, or extract (including bacteriocins extracted therefrom - such as one or more salivaricins) or composition thereof, to an individual so as to at least inhibit microorganisms in the upper respiratory tract such as the oral cavity of the individual (including prophylactic treatment thereof). Tagg et al. further teach using a secondary antibacterial agent (i.e., one or more lantibiotic bacteriocins including various salivaricins such as those instantly claimed);

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pretreating the individual so as to reduce the microbial population by orally administering an antibiotic such as erythromycin prior to the BLIS-producing *S. salivarius* treatment. Tagg et al. also teach the administering various oral composition forms thereof - including in the form of a lozenge, spray, mouth rinse, toothpaste, gargle, capsule, mouthwash, gargle, or toothpaste. In addition, Tagg et al. teaches administering the BLIS-producing *S. salivarius* so as to cause colonization thereof within at least a part of the upper respiratory tract including the mouth (see entire document including pages 2-5, 10-12, and 14-16). Tagg et al. do not expressly teach treating halitosis with such BLIS-producing *S. salivarius* strains, extracts, or compositions thereof, nor other conventional halitosis treatment steps including scraping the tongue and/or gargling/rinsing with chlorine dioxide (with or without orange juice) prior to administering such BLIS-producing *S. salivarius* strains, extracts, or compositions thereto.

Huatan et al. beneficially teach oral formulations which may comprise one or more medicaments including those for treating/preventing halitosis such as lantibiotics (see entire document including, e.g., paragraphs [0047] - [0048]). In addition, Chikindas et al. teach anti-microbial, anti-bad breath (halitosis) oral formulations which may comprise biomolecules such as bacteriocins as an active ingredients therein (see entire document including col 3, lines 51-53).

Kross beneficially teaches treating an individual with halitosis/bad breath including the steps of scraping the tongue so as to reduce extraneous oral debris including bacterial plaque, cellular debris, and food residue therefrom, followed by rinsing the mouth with an aqueous chlorine dioxide solution and/or with an acidic fruit juice such as orange juice so as to effectively reduce/ameliorate oral malodor (see entire document including col 3, line 50 - col 7, line 55 and Examples).

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It would have been obvious to one of ordinary skill in the art to administer the anti-microbial BLIS-producing *S. salivarius* (including strains K12 and/or K30), or extract thereof (such as one or more of the extracted lantibiotic bacteriocins disclosed therein), or a composition comprising such strains and/or extracts, to a subject having halitosis/bad breath because Huatan et al. and Chikindas et al. both beneficially disclose the incorporation of lantibiotics/bacteriocins as active ingredients within oral care formulations useful for treating/preventing halitosis/bad breath (as discussed fully above).

It would also have been obvious to one of ordinary in the art to perform routine conventional steps used to treat halitosis such as scraping the tongue so as to reduce extraneous oral debris including bacterial plaque, cellular debris, and food residue therefrom, followed by rinsing the mouth with an aqueous chlorine dioxide solution and/or with an acidic fruit juice such as orange juice so as to effectively ameliorate oral malodor prior to administering the BLIS-producing *S. salivarius* strains, extracts, or compositions taught by Tagg et al., based upon the beneficial teachings provided by Kross (as discussed fully above). Please also note that treating such an individual would intrinsically control the incidence and/or severity of halitosis caused by the various anaerobic bacteria instantly claimed.

The adjustment of particular conventional working conditions (e.g., also brushing the teeth/tongue with a conventional nonchlorhexidine-containing toothpaste and/or mixing the chlorine dioxide with the orange juice vs. separate administration thereof) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Specification

The disclosure is objected to because the sequences recited therein fail to comply with the requirements of 37 CFR §§ 1.821-1.825, as set forth below:

Applicant is advised that the application is not in compliance with 37 CFR §§ 1.821-1.825.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR §§ 1.821- 1.825) in order to completely respond to this office action.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821-1.825. Applicant must comply with the requirements of the sequence rules (37 CFR §§ 1.821- 1.825) in order to completely respond to this office action.

Specifically, no sequence listing / CRF have been provided which includes the amino acid and nucleic acid sequences set forth on page 7 of the instant specification. In order to satisfy the sequence rules requirements, Applicant needs to also provide an amendment to the instant specification to include reference to the appropriate "SEQ ID NO:" for each amino acid and nucleic acid sequence disclosed therein. In case of any new sequences not properly identified in the instant specification, Applicant is required to provide a substitute computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences that are present in the instant application and encompassed by these rules, a new or substitute paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. § 1.821(e) or 1.821(f) or 1.821(g) or 1.825(d). The instant specification will also need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. See M.P.E.P. 2422.04.

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Alternatively, Applicants may wish to amend the instant specification by appropriately deleting the amino acid and nucleic acid sequence information shown on page 7 thereof since this information does not appear to be pertinent to the instantly claimed invention.

Appropriate correction is required

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970.

The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher R. Tate/
Primary Examiner, Art Unit 1655